Informed consent is defined in Merriam-Webster’s Medical Dictionary as consent to surgery by a patient or to participate in a medical experiment by a subject after achieving an understanding of what is involved. Assent forms must be used for persons under the age of 18. It is important that your informed consent include all the information necessary for the patient to make an educated decision as to whether they wish to participate in the study or not. These guidelines were developed to help you write your informed consent in a clear and conclusive manner.

Attached is a description of the sections that may be included in your informed consent as well as sample consent and assent forms. Please feel free to contact the board if you have any questions concerning the Cherokee Nation Institutional Review Board or our IRB processes.

Cherokee Nation Institutional Review Board Contact Information

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GUIDELINES FOR WRITING AN INFORMED CONSENT

INFORMED CONSENT LAYOUT
The informed consent document should be clearly labeled “Informed Consent” and the following should be easily identifiable:

- The Institution the research/study is affiliated with (as well as the department, if applicable). This may be done in the form of a seal or emblem.
- The Title of the research/study
- The Principal Investigator’s name
- Each page should be numbered (i.e. X of Y)
- There should be a place for the patient to initial on each page in addition to the authorization section on the final page of the form.

INFORMED CONSENT LANGUAGE
It is important to make sure that the informed consent is easily understandable. The following should be considered when writing your form:

- Write in second person
- Use simple language
  - Reading level should be 8th grade or lower
  - Do not use words that are over 3 syllables
  - Do not use sentences that are over 20 words
  - Do not use paragraphs that are over 10 sentences
  - Do not use medical terminology
  - Do not go into excessive detail, just state the important information
- Make it pretty
  - Use large, but not too large, readable fonts
  - Leave an effective amount of white space
  - Bullets, Tables, Timelines, Diagrams, etc are good
  - Avoid using too much bold, italics, underlining, and “quotes”.
  - Use section headings
- Use exact language when appropriate
  - Examples where exact language is appropriate
    - Pharmaceutical companies
      - Standard statement for the injury and compensations section
• Total amount of blood drawn
  • Venipuncture risk statement as well as exact amount of blood drawn for research purposes
• X-ray, CT, MRI, etc risks
  • Proper dose estimate for each procedure and total amounts in the radiation risks statement. This may be presented in a chart.
• Diagrams and study calendars may be included
• Adequately describe the study

**INTRODUCTORY SECTION**

The introductory section should inform the patient that they are being asked to participate in a research study and then explain why. It should tell the patient that the research study will be explained to them in detail by the researcher and that they (the patient) are allowed to ask as many questions as they want at any time they want. The introduction should also list the main person responsible for the study (the PI) and give a number for contacting them so the patient may contact them with further questions. If this is an adult study, as statement such as, “You must be at least 18 years of age to participate in this study” should also be included in the introduction.

**PROJECT DESCRIPTION**

Describe the nature, purpose and duration of the study/project. Make sure it is understandable.

**WHAT WILL BE DONE**

Explain what will happen to the patient, how long they will be involved in this study, describe which part of the study are considered experimental, explain alternative procedures, if any.

**RISK OR DISCOMFORT TO THE PATIENT**

State any expected risks or discomforts for the patient, even if there are none.

**BENEFITS OF PARTICIPATING IN THIS STUDY**

Explain the benefits that the patient or others will receive as a result of this patient’s participation. If there are no expected benefits for the patient, a sentence, such as the
following may be included: “Although there are no benefits to you, researchers will be able to learn more about (insert the topic you are researching here).”

**COMPENSATION**
If a patient is to be compensated for their time, effort, etc, a statement of the manner in which you plan to compensate them may be included here.

**CONFIDENTIALITY**
Explain how you will keep the information gathered as well as the patient’s identity confidential. Consider the following sentence: “Your part in this study is confidential. None of the information will identify you by name. All records will (describe how the records will be maintained).

**If an investigational new drug or device is being used, the subject must be advised that the FDA has the privilege of inspecting records.

**If this study involves information that must legally be reported to government agencies, a statement similar to the following must be included: “Your part in this study is confidential within legal limits. The researchers and the (institution the research is being conducted through) will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be (describe how the records will be maintained).

**If the study is anonymous, it should be stated here. Describe how the subject’s anonymity will be preserved.

**IN CASE OF INJURY TO THE SUBJECT (IF APPLICABLE)**
This section should explain if there is any medical treatment is available if injuries occur and who the patient should contact. Consider the following: “If this study causes you any injury, you should write or call (name of investigator, etc) at (the institution the research is being conducted through) at (the phone number with the area code). You may also contact (give additional contact person, number, address etc).

**DECISION TO QUIT AT ANY TIME**
A sentence similar to the following may be used: “The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in this study, you may quit at any time. You will in no way be penalized for your decision. If you wish to quit, please contact (provide the name and contact information for the PI).”
RIGHTS AND COMPLAINTS
Language such as the following should be included: “If you are not satisfied with the way this study is performed, you may discuss your complaints with (PI’s name) or with (name and phone number of alternate person), anonymously, if you choose.

CONSENT
If the patient agrees to participate, this is the section that needs to be filled out by them. Consider the following: “I have read the Informed Consent and my questions have been answered. My signature on this form means that I understand the information and I agree to participate in this study.” Signatures as well as printed names and the date signed should be acquired from both the patient and the researcher.

**A copy of the signed consent for should be given to the patient for their records.

Sample Informed Consent Forms and Assent Forms are attached.
Sample
INFORMED CONSENT

Department of ________________________________

Title of the Study
Name of PI
Name of Co-Investigator(s), if applicable

Month Day, Year
This Consent form is valid through (Month Day, Year)

Introduction
You are being asked to take part in a research study of......
It is expected that study will last xxxx months or xxxx years .......
This project will be explained to you in detail by....... 
Please feel free to ask any question you may have....... 
If you have questions after you leave you may contact....... 
If applicable: You must be at least 18 years of age.

Project Description
The main reason for this study is to............

What Will Be Done
If you agree to take part in this study, your care will be changed in the following ways...

or

If you agree to take part in this study, we will ask you to do the following things....
**Risk of Discomfort**

*For drug studies include a similar paragraph (your institution may have a standard statement that must be included).* “It is not expected that patients ill have all of these side effects. Other side effects may occur which were not seen before. Side effects are usually temporary and manageable. However, it is possible they could cause serious or fatal disease.”

*For all applicable studies include:* “The study may include risks that are unknown at this time.”

**Benefits of Participating**

*Therapeutic Studies:* “If you decide to take part in this study, there is no guarantee that your health will improve. Also, there are risks as mentioned in the Risk or Discomfort section of this informed consent.

*Non-Therapeutic Studies:* “This study is designed for the research to learn more about *(one or two words).* This study is not designed to treat any illness or to improve your health. Also, there are risks as mentioned in the Risk or Discomfort section of this informed consent.

**Compensation**

You will be paid *(amount)* the form of *(payment type)* at *(time the payment is to be rendered)*.

**Confidentiality**

Your part in this study is confidential within legal limits. The researchers and the *(institution the research is being conducted through)* will protect your privacy, unless they are required by law to report information to the city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. Records that identify you (including your medical records) and the consent form signed by you, may be looked at by the following people:

- Federal agencies that oversee human subject research
- Appropriate Institutional Review Boards
- The investigator and research team for this study
- The sponsor or an agent for the sponsor
- Regulatory officials from the institution where the research is being conducted, to ensure compliance with policies or monitor the safety of the study.

The result of this research may be presented at meetings or in published articles. However, your name will be kept private.
In Case of Injury
If this study cues you any injury, you should write or call (name of investigator) at (institution the research is being conducted through) at (phone number including the area code). You may also contact (include the name and contact information for an additional contact person).

Decision to Quit at Any Time
The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in this study, you may quit at any time. You will in no way be penalized for your decision. If you wish to quit, please contact (provide the name and contact information for the PI).

Rights and Complaints
If you are not satisfied with the way this study is performed, you may discuss your complaints with (PI’s name) or with (name and phone number of alternate person), anonymously, if you choose.

Consent
I have read the Informed Consent and my questions have been answered. My signature on this form means that I understand the information and I agree to participate in this study.

________________________________  ________________________
Signature of Participant               Signature of Researcher

________________________________  ________________________
Printed Name of Participant           Printed Name of Researcher

________________________________  ________________________
Date                                  Date
Sample

ASSENT FORM

Department of ____________________________________

Title of the Study

Name of PI

Name of Co-Investigator(s), if applicable

Month Day, Year

This Consent form is valid through (Month Day, Year)

This form should be written in language appropriate to the developmental level of the minor subject. Introductory section should begin with words of this effect.

My name is _________________. We are asking you to take part in a research study because we are trying to learn more about (this study). We will explain the project to you in detail. You should feel free to ask questions. If you have more questions about this study later, please call (contact person), the person responsible for this study, at (phone number).

Description

(Describe the nature of the study and the purpose of the research. Special attention must be given to processes for quitting or withdrawal from research. The researcher should be cognizant of signs of discomfort shown by the child throughout the study, and periodically inquire about the child’s feelings. Include procedures for withdrawal that address these considerations.)

What Will Be Done

If you agree to be in this study, you will be asked to (here describe, in lay terms, what will happen to the subject, the duration/frequency of the subject’s involvement, note
any parts of the study that are considered experimental and explain alternative procedures, if any exist).
Risk or Discomfort
(Explain any risks or discomforts, physical or otherwise, that might reasonably be expected as a result of participation; if none are expected, state that here)

Benefits of this Study
(Describe anticipated benefits to the subject, or to others, of the study. IF there is no foreseeable direct benefit to the subject, include a sentence to this effect:) Even though there will be no direct benefit to you for taking part in this study, w may learn more about (one or two words).

Confidentiality
(Describe the manner in which subject confidentiality will be maintained.) Your part in this study is (confidential/anonymous) (as applicable). (Use words to this effect, as applicable): No one else will know if you were in this study and no one else can find out what answers you gave. We will keep all the records for this study (describe how/where records are to be stored/maintained).

Decision to Quit at Any Time
(Using words to this effect): You might want to talk this over with your parents before you decide whether or not to be in this study. The decision to be part of this research is up to you. You do not have to participate. We will also ask you parents to give their permission for you to take part in this study, but even if your parents say “Yes,” you can still decide not to do this. If you do decide to participate, you can always drop out of the study at any time. Whatever you decide will not be held against you in any way. No one will be upset if you don’t want to participate or even if you change your mind later and want to stop. If you want to quit the study, just let (contact person/phone number) know or ask one of your parents to call us.

Consent
Remember, you can ask any questions you may have about this study. If you have a question later that you didn’t think of now, you can call me at (phone number) or ask me next time. Would you like to read or hear about this study again before you make your decision?
Signing your name at the bottom of this form means that you have read or listened to what it says and you understand it. Signing this form also means that you agree to participate in this study and your questions have been answered. You and your parents will be given a copy of this form after you have signed it.

__________________________________________________________
Signature of Participant                                      Signature of Researcher

__________________________________________________________
Printed Name of Participant                                   Printed Name of Researcher

__________________________________________________________
Date                                                          Date